Consent and Authorization Form

17-1176 Consent
June 2019
Kyle Rove

Principal Investigator: **Kyle Rove, MD**
COMIRB No: **17-1176**
Version Date: **June 2019**

Study Title: **Multicenter Pilot and Exploration Study of Enhanced Recovery After Surgery (ERAS) in Patients Undergoing Urologic Reconstructive Surgery**

You are being asked to be in a research study. 'You' refers to the pediatric patient. This form provides you with information about the study. A member of the research team will describe this study to you and answer all of your questions. Please read the information below and ask questions about anything you don't understand before deciding whether or not to take part.

Why is this study being done?

The purpose of this research study is to evaluate procedures we have implemented to potentially speed up recovery after urologic surgery. We are interested in speed of recovery (how quickly pain improves, length of time in the hospital, and need for additional pain control).

You are being asked to be in this research study because you or your child is going to have bladder surgery requiring hospitalization. Up to 60 people will participate in the study at Children's Hospital Colorado. The study is being done at other sites around the United States. Approximately 500 people will take part in this study across all sites.

What happens if I join this study?

If you join the study, we will ask you to complete a survey about yourself before your surgery and another afterwards. We will collect health information from your medical record about your surgery and your recovery continually for 1 year after your surgery. You may skip any question which makes you uncomfortable.

What are the possible discomforts or risks?

One risk of participating in this study is that confidential information about you may be accidentally disclosed. We will use our best efforts to keep the information about you secure.

To help protect your confidentiality, we will assign a study identification number to your data. We will separate information that identifies you from the rest of the study data and store all the data securely in an electronic database. If we write a report or article about this study or share the study data set with others, we will do so in such a way that you cannot be directly identified.

There are no other known risks from being in this study, and you will not benefit personally. However, we hope that others may benefit in the future from what we learn as a result of this study.

Will I be paid for being in the study? Will I have to pay for anything?

You will not have any costs for being in this research study and you will not be paid.

Is my participation voluntary?

Taking part in this study is voluntary. You have the right to choose not to take part in this study. If you choose to take part, you have the right to stop at any time. If you refuse or decide to withdraw later, you will not lose any benefits or rights to which you are entitled.

If there are any new findings during the study that may affect whether you want to continue to take part, you will be told about them.

Who do I call if I have questions?

The researcher carrying out this study is Dr. Kyle Rove. You may ask any questions you have now. If you have questions later, you may call Dr. Kyle Rove at 720-777-6146.

You may have questions about your rights as someone in this study. You can call Dr. Kyle Rove with questions. You can also call the Multiple Institutional Review Board (IRB). You can call them at 303-724-1055.

Who will see my research information?

The University of Colorado Denver and its affiliated hospital(s) it works with have rules to protect information about you. Federal and state laws including the Health Insurance Portability and Accountability Act (HIPAA) also protect your privacy. This part of the consent form tells you what information about you may be collected in this study and who might see or use it.
The institutions involved in this study include:

- University of Colorado Denver
- Children's Hospital Colorado

Children's Hospital Colorado shares a medical record system with the Barbara Davis Center and PedsConnect; therefore, it is also possible that other healthcare professionals could view your information.

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We cannot do this study without your permission to see, use and give out your information. You do not have to give us this permission. If you do not, then you may not join this study.

We will see, use and disclose your information only as described in this form and in our Notice of Privacy Practices; however, people outside the University of Colorado Denver and its affiliate hospitals may not be covered by this promise.

We will do everything we can to keep your records a secret. It cannot be guaranteed.

The use and disclosure of your information has no time limit. You can cancel your permission to use and disclose your information at any time by writing to the study's Primary Investigator, at the name and address listed below. If you do cancel your permission to use and disclose your information, your part in this study will end and no further information about you will be collected. Your cancellation would not affect information already collected in this study.

Kyle Rove, MD
Children's Hospital Colorado
13123 East 16th Avenue B463
Aurora, CO 80045

Both the research records that identify you and the consent form signed by you may be looked at by others who have a legal right to see that information.

- Federal offices such as the Food and Drug Administration (FDA) that protect research subjects like you.
- People at the Colorado Multiple Institutional Review Board (COMIRB)
- The study doctor and the rest of the study team.
- Officials at the institution where the research is being conducted and officials at other institutions involved in this study who are in charge of making sure that we follow all of the rules for research

The investigator (or staff acting on behalf of the investigator) will use your information for the research outlined in this consent form. They will also make *all or some* of the following health information about you collected in this study available to:

- St. Louis Children's Hospital
- Washington University in St. Louis

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Your information may be used and disclosed, to do the research, to study the results, and to make sure that the research was done right.

We might talk about this research study at meetings. We might also print the results of this research study in relevant journals. But we will always keep the names of the research subjects, like you, private.

You have the right to request access to your personal health information from the Investigator.

Information about you that will be seen, collected, used and disclosed in this study:

- Name and Demographic Information (age, sex, ethnicity, address, phone number, etc.
- Portions of your previous and current Medical Records that are relevant to this study, including but not limited to Diagnosis(es), History and Physical, laboratory or tissue studies, radiology studies, procedure results
- Research Visit and Research Test records

Agreement to be in this study and use my data

I have read this paper about the study or it was read to me. I understand the possible risks and benefits of this study. I understand and authorize the access, use and disclosure of my information as stated in this form. I know that being in this study is voluntary. I choose to be in this study: I will get a signed and dated copy of this consent form.

Child's Name _____Child's Date of Birth_____

Parent Signature:_____ Date:_____

Print Name:_____

Subject (age 13-18 years) Signature: _____ Date_____

Consent form explained by:_____ Date:_____

Print Name: _____

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Signature Line for witness for consent of non-reading subjects and consent using a short form, if you requested such consent procedures (see Application section L)]

_____ Date_____

Print Name: _____

Witness of Signature ☐

Witness of consent process ☐

Rove KO, *et al. BMJ Open* 2020; 10:e039035. doi: 10.1136/bmjopen-2020-039035